IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION

STATE OF TENNESSEE, STATE OF ALABAMA, STATE OF ARKANSAS, STATE OF GEORGIA, STATE OF IDAHO, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MONTANA, STATE OF NEBRASKA, STATE OF NORTH DAKOTA, STATE OF OHIO, STATE OF SOUTH CAROLINA, STATE OF SOUTH DAKOTA, STATE OF WEST VIRGINIA, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOROTHY A. FINK, in her official capacity as Acting Secretary of the U.S. Department of Health and Human Services; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF CIVIL RIGHTS, *Defendants.*	Civil Action No. 3:25-cv-00025 Judge Katherine A. Crytzer Magistrate Judge Jill E. McCook

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PRELIMINARY RELIEF

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INTRODUCTION

The "Law of Unintended Consequences" holds that "[w]hether or not what you do has the effect you want, it will have three at least you never expected, and one of those usually unpleasant." Robert Jordan, *The Path of Daggers* 313 (1st ed. 1998). Case in point: the U.S. Department of Health and Human Services' ("HHS") *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (April 26, 2024) (the "Final Rule"). Promulgated explicitly in reaction to the Supreme Court's decision returning abortion regulation to the States in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), the Final Rule is meant to pump the brakes on States' investigating and prosecuting violations of state laws protecting fetal life. That disruption to the post-*Dobbs* federal-state balance is unlawful alone, but the Final Rule does much more. Most relevant: It halts state investigations into fraud, abuse, and adverse patient outcomes unrelated to a State's limits on abortion.

The Final Rule warps the Health Insurance Portability and Accountability Act ("HIPAA") to impose barriers on the use and disclosure of protected health information ("PHI") about "reproductive health care," which it defines broadly enough to encompass almost any care conceivable. 89 Fed. Reg. at 32,978. Before using or disclosing basic, vital information for public-health and fraud investigations, HIPAA-covered entities and state investigators each must navigate a complex morass of legal judgments to ensure that the information is not sought for a prohibited purpose, including to "investigat[e]" lawfully obtained "reproductive health care." *Id.* at 33,063. This places health professionals in the position of making legal determinations that have confounded even Article III courts and requires investigators to make blind predictions under threat of criminal liability about where an investigation will lead before it has begun. Even if information is ultimately disclosed, that is only after significant delay and disruption to the investigative process.

As a district court in Texas has already suggested, Congress did not authorize HHS to use HIPAA as a roadblock to "limit" or "slow[] down" state investigations. *Purl v. HHS*, No. 2:24-CV-

228-Z, 2024 WL 5202497, at *6-10 (N.D. Tex. Dec. 22, 2024). Congress mandated the opposite: "Nothing in [HIPAA] shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b). In addition to exceeding HHS's authority under HIPAA, the Final Rule is arbitrary and capricious on several fronts, including employing a new presumption of lawful care that places a thumb on the scale against complying with state records requests.

Plaintiffs—the States of Tennessee, Alabama, Arkansas, Georgia, Idaho, Indiana, Iowa, Louisiana, Montana, Nebraska, North Dakota, Ohio, South Carolina, South Dakota, and West Virginia—now seek preliminary relief prohibiting application of the Final Rule against their HIPAA-covered entities and state investigators. Preliminary relief is necessary to prevent the Plaintiff States from continuing to suffer the substantial and irreparable sovereignty and compliance harms their declarations detail. The public interest also favors the Plaintiff States' conducting effective public-health investigations and enforcing duly enacted laws and regulations prohibiting waste, fraud, and abuse. HHS, on the other hand, would suffer no harm from an order enforcing HIPAA's proper scope. In the interest of judicial economy, and because this Administrative Procedure Act ("APA") case involves pure questions of law requiring no further factual development, the Plaintiff States also seek summary judgment and request that the Court "set aside" the Final Rule as unlawful. 5 U.S.C. § 706(2).[1]

BACKGROUND

I. HIPAA and the Privacy Rule.

Congress enacted HIPAA to "improve portability and continuity" and "simplify the administration of health insurance." Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996). To that end,

[1] Because counsel for Defendants has not yet appeared, the Plaintiff States have provided copies of their motion, this accompanying memorandum, and their supporting exhibits to counsel representing Defendants in related cases pending in the U.S. District Court for the Northern District of Texas.

Congress "encourag[ed] the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain [patient] health information." Pub. L. No. 104-191 § 261. Given the sensitivity of patients' health information, Congress made it unlawful for anyone "knowingly" to "use[]," "obtain[]," or "disclose[] individually identifiable health information" without authorization. 42 U.S.C. § 1320d-6(a). Violating HIPAA carries serious criminal consequences, including fines and jail time. *Id.* § 1320d-6(b).

Congress instructed HHS upon HIPAA's enactment to promulgate initial enforcing regulations to cover the "rights that an individual who is a subject of individually identifiable health information should have," "procedures that should be established for the exercise of such rights," and "uses and disclosures of such information that should be authorized or required." Pub. L. No. 104-191 § 264(b)(1)-(3). But HHS did not have carte blanche, and Congress was particularly concerned with the relationship between HIPAA and state laws. Thus, any regulation HHS promulgated could not preempt a contrary state law with "more stringent" requirements for protecting health information. *Id.* § 264(c)(2). Nor could HHS construe HIPAA "to invalidate or limit" States' authorities to police public-health matters. 42 U.S.C. § 1320d-7(b).

HHS thus promulgated *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (the "Privacy Rule"). The Privacy Rule's "major goal" "is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being."[2] The Privacy Rule bars the use or disclosure of PHI without the patient's approval except for specified purposes, including: for law enforcement; in response to lawful process; and for conducting public health oversight, surveillance, or investigation. *See* 45 C.F.R. § 164.512 (2023).

[2] *See* HHS Office for Civil Rights, *Summary of the HIPAA Privacy Rule* 1 (May 13, 2003), https://www.hhs.gov/sites/default/files/privacysummary.pdf.

The "law enforcement purpose[s]" encompassed by the Privacy Rule include disclosing as the law otherwise requires, identifying or locating an individual, protecting victims, investigating deaths, and reporting crime in emergencies. *Id.* § 164.512(f)(1)-(4), (6). The Privacy Rule requires that law enforcement requests for PHI pursuant to a court order, subpoena, or administrative process be for "information [that] is relevant and material to a legitimate law enforcement inquiry," "specific and limited in scope to the extent reasonably practicable," and not "reasonably" satisfied with "[d]e-identified information." *Id.* § 164.512(f)(1)(ii)(C). HHS "designed" this three-part test to preserve patient privacy without "unduly compromis[ing]" States' authorities. 65 Fed. Reg. at 82,683.

II. States Investigate Fraud, Abuse, and Adverse Patient Outcomes to Protect Public Health and Guard the Public Fisc.

The U.S. Constitution's "federal system" provides the "National Government" only limited powers; the remainder, the "States and the people retain." *Bond v. United States*, 572 U.S. 844, 854 (2014). Chief among the States' reserved powers is the traditional power "to enact legislation for the public good"—i.e., the "police power." *Id.* (citation omitted). States have "great latitude under their police powers to legislate as to the protection of lives, limbs, health, comfort, and quiet of all persons." *Gonzalez v. Oregon*, 546 U.S. 243, 270 (2006) (citation omitted).

For example, States directly "regulate the practice of medicine." *McNaughton v. Johnson*, 242 U.S. 344, 348-49 (1917). Indeed, "[t]here is perhaps no profession more properly open to … regulation" by States. *Watson v. Maryland*, 218 U.S. 173, 176 (1910). States limit *who* may deliver health services within their borders. *See, e.g.*, Tenn. Code Ann. §§ 63-6-201, -203, -213, -214. They prescribe *how* those health professionals may practice. *See, e.g.*, *id.* § 63-1-155 (authorizing telehealth); *id.* § 63-6-218 (granting good-Samaritan immunity). States also regulate *what types* of treatments or care plans health professionals may pursue. *See, e.g.*, *id.* § 33-8-315 (outlawing lobotomy); *id.* § 53-11-308(e), (f) (regulating opioid dispensing). And, more generally, States over the years have developed public-health laws and sophisticated infrastructures to protect the public from tuberculosis, *id.* §§ 68-9-101

to -116, sexually transmitted diseases, *id.* §§ 68-10-101 to -118, and all manner of public health concerns, *see generally id.*, Title 68.

States also "regulate consumer products … to promote public health and safety," which "falls neatly within [their] traditional police powers." *HW Premium CBD, LLC v. Reynolds*, No. 4:24-CV-00210-SMR-SBJ, 2024 WL 3548320, at *6 (S.D. Iowa July 25, 2024). The Consumer Protection Division of the Tennessee Attorney General's office, for its part, has pursued investigations and enforcement against health professionals who are suspected of harming patients with unfair or deceptive business practices. *See* Decl. of Kelley Groover ¶¶ 5, 12 (Exhibit A). Currently, the office is pursuing a case in which a fertility clinic shuttered overnight, and the owner is suspected of failing to properly secure or maintain cryogenic tanks that held hundreds of irreplaceable genetic specimens. *Id.* ¶ 6.

States also maintain responsibility for funding, implementing, and monitoring compliance with important federally funded programs, including Medicaid and Medicare. In that role, States often coordinate with federal partners to maintain standards of care, protect vulnerable populations, and ensure proper use of federal-program funding. For example, Tennessee's Health Facilities Commission ("Health Facilities") "conducts certification and compliance surveys of health facilities that participate in Medicare to ensure the facility maintains compliance with conditions of program participation." Decl. of Katherine Zeigler ¶ 3 (Exhibit B); *see also* 42 C.F.R., Part 482. Surveys are often conducted pursuant to a patient complaint about care or conditions at a facility. Zeigler Decl. ¶ 3. States also pursue civil and criminal investigations of Medicaid fraud. *See* Tenn. Code Ann. § 71-5-183(a); *id.* § 71-5-2508. This includes "investigat[ing] and refer[ing] for prosecution … complaints of abuse, neglect, and financial exploitation of medicaid recipients in any setting." *Id.* § 71-5-2508.

States' ability to effectively enforce these state and federal laws depends on their timely access to certain patient records. *See* Decl. of Kevin Kreutz ¶¶ 4-6 (Exhibit C); Zeigler Decl. ¶¶ 9, 15; Groover Decl. ¶¶ 9-11. For decades, States have obtained this information under the Privacy Rule

without significant hinderance. *See, e.g.*, Zeigler Decl. ¶ 5. But when targets have denied information requests, investigators have had to seek relief through "resource intensive and time consuming" court proceedings that "can delay an investigation by months or even years." Groover Decl. ¶ 13.

III. HHS Proposes New HIPAA Regulations After *Dobbs*.

In June 2022, the U.S. Supreme Court "return[ed]" abortion regulation "to the people and their elected representatives" by holding that the federal constitution does not require States to permit abortions. *Dobbs*, 597 U.S. at 259. *Dobbs* triggered state laws across the country set to take effect if *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992) were overruled. Under those laws, and other state laws enacted after the *Dobbs* decision, many States now generally prohibit abortions unless performed to address a serious health risk to the mother. *See, e.g.*, Tenn. Code Ann. § 39-15-213; N.D. Cent. Code Ann. § 12.1-19.1-02.

According to HHS, these developments "created new concerns about the privacy of PHI related to reproductive health care." *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 88 Fed. Reg. 23,506, 23,519 (Apr. 17, 2023) (the "Proposed Rule"). Thus, HHS proposed placing novel conditions on the use and disclosure of "reproductive health care" information, which HHS broadly defined as information on "all types of health care related to an individual's reproductive system." *See id.* at 23,521-27. Among other examples, HHS proposed that investigators requesting PHI from a covered entity "that is potentially related to reproductive health care" must sign an attestation under threat of criminal penalty that the "use or disclosure would not be for a purpose prohibited" by the rule. *Id.* at 23,535. HHS further proposed to require that the request recipient evaluate those attestations and determine whether the information is sought to investigate conduct that, in the recipient's judgment, was legal when rendered. *Id.* at 23,535-36.

HHS's unprecedented proposal garnered more than 25,000 comments. A coalition of nineteen States—many plaintiffs here—filed a comment letter opposing the Proposed Rule. Dkt. #1-2.

The States explained that the Proposed Rule "trespasses on and interferes" with "core state authority" by precluding "States' ability to obtain evidence that could reveal violations of their laws." *Id.* at 8. Such interference with States' traditional powers to investigate violations of their laws, the States explained, meant that the rule "cannot be reconciled with our constitutional design." *See id.* at 8-10.

IV. HHS Promulgates the Final Rule and State Investigations Grind to a Halt.

Undeterred, HHS promulgated the Final Rule in April 2024.[3] 89 Fed. Reg. at 32,976. The Final Rule built on the Proposed Rule's broad definition of "reproductive health care," "clarif[ying]" that the term encompasses the "full range of health care related to an individual's reproductive health," *id.* at 33,005, including "all matters relating to the reproductive system and to its functions and processes," *id.* at 33,063. The Final Rule also carried forward the proposed barriers to using and disclosing "reproductive health care" information even though those barriers "may affect certain state interests in obtaining PHI to investigate potentially unlawful" conduct. *Id.* at 32,995.

The Final Rule prohibits the disclosure of information about "reproductive health care" for at least three specific purposes:

> (1) [t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[;]
>
> (2) [t]o impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[; or]
>
> (3) [t]o identify any person [for these purposes].

45 C.F.R. § 164.502(a)(5)(iii)(A). Thus, the Final Rule restricts disclosure of "reproductive health care" information if "investigation" or "liability" attaches for the "mere act" of seeking, procuring, or facilitating certain medical services.

[3] Although the Final Rule became effective in June 2024, compliance generally was not required until late December 2024. 89 Fed. Reg. at 32,976.

The Final Rule's disclosure bar applies only if state or federal law deems the medical service "lawful" under the circumstances it was provided. The Final Rule states that the bar applies only if the covered entity "reasonably determine[s] that one or more of the following conditions exists":

> (1) [t]he reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided[;]
>
> (2) [t]he reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided[; or]
>
> (3) [t]he presumption [that the "reproductive health care" at issue was lawful] applies.

Id. § 164.502(a)(5)(iii)(B). The Final Rule creates a presumption that "reproductive health care" provided by another person was lawful. *See id.* § 164.502(a)(5)(iii)(B)(3) & (C). The presumption is overcome only if (1) the covered entity has actual knowledge that the reproductive health care was not lawful or (2) the person requesting disclosure of PHI supplies "[f]actual information … that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.* § 164.502(a)(5)(iii)(C). The Final Rule leaves the complex determination whether the information is sought for a prohibited purpose up to the covered entity—which is often the one under investigation.

Under the Final Rule, many requests for information must include an "attestation" meeting strict requirements set by HHS. 45 C.F.R. § 164.509(a)(1); *see id.* § 164.512. "The requesting agency must say the information will not be used for a prohibited purpose; must not contain any extra, non-required statements; must be believable to a reasonable covered entity; must contain a specific description of the sought information; must contain a statement that a covered entity could be subject to penalties for a HIPAA violation; must be in plain language; and must be signed." *Purl*, 2024 WL 5202497, at *9; Compl. ¶ 86 (example attestation). If the attestation is deficient, disclosure is prohibited by the Final Rule—and the HIPAA-covered entity bears the risk HHS will later determine the

attestation was deficient. *See* 45 C.F.R. § 164.509(a)(2).

At the same time, though, the Final Rule does not provide investigators with effective recourse if a covered entity deems an attestation invalid for whatever reason. Instead, the Final Rule's disclosure limits on "reproductive health care" information travel in only one direction. The Final Rule does not "prevent regulated entities from using or disclosing PHI for the purpose of defending themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care." 89 Fed. Reg. at 33,011. So the Final Rule allows disclosure to *defend against* a claim or prosecution involving "reproductive health care," but inhibits investigators from obtaining similar information to *enforce* violations of state laws or protect public health.

Though commenters warned HHS about the Final Rule's potential impact on state enforcement authorities, *see* Dkt. #1-2 at 8-11, 14; Comment of Ethics & Pub. Pol'y Ctr. 10-18 (Exhibit D), the agency brushed off such concerns, *see, e.g.*, 89 Fed. Reg. at 33,012. And once the Final Rule's mandates took hold, the impact on state investigations became clear and immediate. To name just one, Health Facilities received complaints that substandard care at a psychiatric facility resulted in a patient's death. *See* Zeigler Decl. ¶ 8. Although the alleged misconduct had no obvious connection to reproductive health care, investigators were denied access to vital patient records without an attestation. *Id.* ¶¶ 8-11. Investigators have reasonably declined to provide that attestation given the Final Rule's vague scope and uncertain interactions with other authorities, *id.* ¶ 12, halting the investigation. Other investigations have similarly faced hurdles or outright stoppage because of the Final Rule's disclosure requirements. *See* Kreutz Decl. ¶¶ 18-21; Groover Decl. ¶¶ 7-8; Decl. of Larry Johnson, Jr. ¶¶ 9-15 (Exhibit E); Decl. of Marina Spahr ¶¶ 16-20 (Exhibit F); Decl. of Brannon Traxler ¶¶ 19-21 (Exhibit G); Decl. of Michael Targia ¶¶ 18-20 (Exhibit H); Decl. of Ashley Klenski ¶¶ 16-20 (Exhibit I); Decl. of Tonya Joiner ¶¶ 7-11 (Exhibit J); Decl. of Nicholas Dietz ¶¶ 17-22 (Exhibit K); Decl. of Charity Menefee ¶¶ 18-22 (Exhibit L); Decl. of Stephanie Azar ¶¶ 12-16 (Exhibit M); Decl. of Jordan

Stover ¶¶ 7-11, 15-18 (Exhibit N); Decl. of Amy Osborne ¶¶ 9-11 (Exhibit O).

LEGAL STANDARDS

The Plaintiff States seek both preliminary relief under Federal Rule of Civil Procedure 65 and 5 U.S.C. § 705, and, as permitted by Rule 65(a)(2), summary judgment under Rule 56. Whether to grant preliminary relief turns on four factors: "(1) whether the moving party has shown a likelihood of success on the merits; (2) whether the moving party will be irreparably injured absent an injunction; (3) whether issuing an injunction will harm other parties to the litigation; and (4) whether an injunction is in the public interest." *Vitolo v. Guzman,* 999 F.3d 353, 360 (6th Cir. 2021); *see Ohio ex rel. Celebrezze v. Nuclear Regul. Comm'n*, 812 F.2d 288, 290 (6th Cir. 1987) (same under 5 U.S.C. § 705).[4] Likelihood of success is generally "the most important factor of a preliminary injunction analysis." *Higuchi Int'l Corp. v. Autoliv ASP, Inc.*, 103 F.4th 400, 409 (6th Cir. 2024).

Typically, the lawfulness of an agency action is resolved at summary judgment because "resolution of the matter does not require fact finding." *Harkness v. Sec'y of the Navy*, 174 F. Supp. 3d 990, 1004 (W.D. Tenn. 2016) (cleaned up) (citation omitted). The APA's standard of review governs motions for summary judgment in APA cases. *See Sierra Club v. Slater*, 120 F.3d 623, 632 (6th Cir. 1997). Rather than "reviewing the record for disputed facts that would preclude summary judgment," the court is to assess the lawfulness of the agency's action based on the "evidence in the administrative record." *Ardmore Consulting Grp., Inc. v. Contreras-Sweet*, 118 F. Supp. 3d 388, 393 (D.D.C. 2015) (citation omitted). If the agency exceeded its statutory authority or acted in an arbitrary and capricious manner, the court must "hold unlawful and set aside" the challenged action. 5 U.S.C. § 706(2)(A), (C).

ARGUMENT

The issues here—HHS's statutory authority to promulgate the Final Rule and whether HHS

[4] "Courts—including the Supreme Court—routinely stay already-effective agency action under Section 705." *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022) (collecting cases).

acted arbitrarily and capriciously in doing so—can be resolved on the administrative record without further factual development. *See, e.g.*, *PayPal, Inc. v. CFPB*, 728 F. Supp. 3d 31, 38 (D.D.C. 2024). Rather than expend judicial resources on two rounds of near-identical briefing at the preliminary-relief and summary-judgment stages, the Plaintiff States respectfully now seek a judgment finally "set[ting] aside" the Final Rule as unlawful. Such combined motions practice is common in APA cases.[5] At a minimum, given the Plaintiff States' ongoing harm, the Court should preliminarily enjoin application of the Final Rule's disclosure requirements against the Plaintiff States, their HIPAA-covered entities and state investigators, or stay the Final Rule under § 705, pending final judgment.

I. HHS's Final Rule Is Unlawful.

A. The Plaintiff States have standing to sue.

There is "little question" that the Plaintiff States—whose health agencies and state-run health facilities are HIPAA-covered entities, and whose investigative agencies regularly request HIPAA-protected PHI—have standing to challenge the Final Rule, as they are the "object of the action … at issue." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992). Indeed, the Plaintiff States easily satisfy all three elements for Article III standing—injury, traceability, and redressability. *See id.* at 560-61.

The Plaintiff States' injuries are two-fold. First, States have "a recognized quasi-sovereign interest in the health … of their populaces," *Kentucky v. Biden*, 23 F.4th 585, 599 (6th Cir. 2022), and "[p]erhaps the clearest example of traditional state authority is the punishment of local criminal activity." *Bond*, 572 U.S. at 858. But the Final Rule impedes state investigations meant to enforce civil and criminal laws that protect public health and the public fisc. Such "interference with a state's sovereign 'power to create and enforce a legal code' is sufficient to establish Article III standing." *Tennessee v. U.S. Dep't of Educ.*, 104 F.4th 577, 591 n.11 (6th Cir. 2024) (citation omitted). Indeed, the Final Rule's

[5] *See, e.g.*, *1306 Lounge, LLC v. SBA*, No. 22-cv-3320-RBW, 2024 WL 4987025, *3-5 (D.D.C. Dec. 5, 2024); *Chamber of Com. of the United States v. DHS*, 504 F. Supp. 3d 1077, 1081 (N.D. Cal. 2020); *Pol'y & Rsch., LLC v. HHS*, 313 F. Supp. 3d 62, 71 (D.D.C. 2018).

explicit concern is regulating States' enforcement of laws protecting fetal life, and "when a federal regulation purports to preempt state law," States have "a sovereign interest to sue the United States." *Kentucky*, 23 F.4th at 598 (collecting cases). Second, the Final Rule's vague and overbroad disclosure conditions have required States to expend significant time and resources assessing their systems for disclosing and requesting HIPAA-protected information—particularly because improperly using or disclosing PHI carries significant criminal liability. *See, e.g.*, Traxler Decl. ¶¶ 17-18; Spahr Decl. ¶ 15-18. That's the result the Final Rule itself predicted: HHS "anticipate[d] that covered entities will need to develop new or modified policies and procedures for the new requirements." 89 Fed. Reg. 33,056. Because HHS is protected by sovereign immunity, these compliance costs are unrecoverable and constitute injury "for purposes of Article III" standing. *Kentucky v. Yellen*, 54 F.4th 325, 342-43 (6th Cir. 2022); *see Purl*, 2024 WL 5202497, at *5-6.

The Plaintiff States' sovereignty and fiscal injuries are traceable to the Final Rule. Investigators successfully obtained necessary records through requests under the Privacy Rule because it was "designed" to balance patient privacy interests against States' sovereign interests in "law enforcement." 65 Fed. Reg. at 82,683. That investigators now cannot obtain similar information without significant delay or resistance is directly attributable to the Final Rule. *See* Zeigler Decl. ¶ 11. As HHS predicted, the Final Rule's "significantly more difficult" standards "unduly compromise[]" "law enforcement's ability to protect the public interest." 65 Fed. Reg. at 82,683. And without the sea change brought by the Final Rule, States could continue to operate under their long-standing HIPAA protocols rather than update systems and trainings to account for the Final Rule's mandates. *See Tennessee*, 104 F.4th at 590; *see also Purl*, 2024 WL 5202497, at *5-6. Thus, Plaintiff States' injuries are traceable to the Final Rule and would be redressed by an order setting it aside. *See Tennessee*, 104 F.4th 590-91, 595.

B. The Final Rule exceeds HHS's statutory authority.

HHS's "power to act and how they are to act is authoritatively prescribed by Congress." *City*

of Arlington v. FCC, 569 U.S. 290, 297 (2013). So the question here is whether HHS "has stayed within the bounds of its statutory authority." *Id.* To answer that question, courts must begin with the statute's text to "determin[e] the meaning of statutory provisions." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024). Because nothing in HIPAA permits HHS to craft special disclosure requirements for "reproductive health care" information, the Final Rule unlawfully exceeds the agency's authority.

1. Recognizing States' traditional police powers over public health and welfare, Congress explicitly mandated that "[n]othing in [HIPAA] shall be construed to invalidate or *limit* the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d–7(b) (emphasis added). Thus, whether the Final Rule "exceeds statutory authority turns on the meaning of 'limit' in HIPAA." *Purl*, 2024 WL 5202497, at *7. HHS is not entitled to deference on what "limit[s]" are allowed by the rule of construction. Instead, this Court's interpretation of the statute's "single, best meaning" must control. *Loper Bright*, 603 U.S. at 400.

HIPAA does not define "limit," so it must be given its "ordinary, common meaning as understood by the people it governs." *Purl*, 2024 WL 5202497, at *8 (collecting cases). A "limit" is "something that bounds, restrains, or confines." *Limit*, Merriam-Webster's Collegiate Dictionary 674 (10th ed. 2001). It is a "confining or restricting agent, or influence." *Limit*, American Heritage Dictionary of the English Language 1015 (4th ed. 2000). Thus, "[a]ll agree that something is *limited* when restrictions, restraints, or curtailments are imposed." *Purl*, 2024 WL 5202497, at *8. So a "limit" need not amount to a complete bar. "[L]aws that curtail or restrain the activity—even if the activity is not completely prohibited—*limit* the activity through imposing obstructions to the relevant activity." *Id.*

So does the Final Rule restrict, restrain, or curtail States' "authority, power, or procedures … for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health"? Yes, of course. States—in both their capacity as HIPAA-covered entities and as investigative

authorities—now must navigate a "labyrinth of criteria" to police these public concerns. *See Purl*, 2024 WL 5202497, at *7 (citation omitted). The upshot is a regime that imposes several new hurdles that slow and sometimes block lawful state investigatory and public-health enforcement activities.

First, the Final Rule requires covered entities to "screen requested PHI for whether it contain[s] information potentially related to reproductive health care." 89 Fed. Reg. at 33,060. That process is no small matter: The Final Rule's definition of "reproductive health care" is intentionally broad, meaning the necessary screening will be extensive because almost any patient record could be "potentially related" to the "functions and processes" of the reproductive system. 45 C.F.R. § 160.103. The threat of criminal liability, moreover, drives covered entities to err on the side of determining that some requested information "potentially relate[s]" to "reproductive health care" as broadly defined in the Final Rule, even when the connection is far from obvious. For example, a dialysis center refused to disclose information without an attestation under the Final Rule. Zeigler Decl. ¶ 10.

Second, a determination that "reproductive health care" information is implicated necessitates a second inquiry: Whether the requesting state or local agency is (i) "conduct[ing] a criminal, civil, or administrative investigation" or seeking to "impose criminal, civil, or administrative liability" for (ii) "the mere act of seeking, obtaining, providing, or facilitating reproductive health care." 89 Fed. Reg. at 33,063. So a request recipient must evaluate the investigators' motive—apparently by using some subjective sense of whether an agency is truly targeting waste, fraud, and abuse, or instead the provision of reproductive health care that HHS favors. How that works, the Final Rule doesn't say. Rather, it leaves it, in some cases, to the target of the investigation to determine.

Third and further complicating things, the Final Rule's disclosure bar applies only if the medical service was "lawful" under the circumstances it was provided. *Id.* This legality determination is yet another impermissible "limit" that delays and frustrates investigations. *Purl*, 2024 WL 5202497, at *8-9. Indeed, HHS itself recognized that "situations may arise where a regulated entity reasonably

determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (*e.g.*, law enforcement) reasonably believes otherwise." 89 Fed. Reg. at 32,993. Of course, covered entities generally "are not prepared or equipped to make nuanced legal judgments." *Purl*, 2024 WL 5202497, at *8. Yet the Final Rule puts them in the position of making legal judgments in areas of the law that are unsettled and ever changing. For example, the Final Rule "would require a doctor to navigate whether an abortion was 'legal' under EMTALA … before disclosing and risking liability under HIPAA" even though "[s]uch questions [have] confounded Article III courts." *Id.* at *9 (citation omitted). And that is to say nothing of the "fluctuat[ion]" in HHS's understanding of the legality of different forms of "reproductive health care" from administration to administration. *See id.*; *compare* Compl. ¶ 71 (detailing Biden Administration's view that federal law protects abortion and gender-transition interventions in minors), *with* Tenn. Code Ann. § 39-15-213, *and* Tenn. Code Ann. § 68-33-103 (restricting same). Forcing covered entities and requesting agencies to navigate thorny legal questions under threat of criminal liability chills States' "authority, power, [and] procedures" in a way HIPAA nowhere contemplates. *See id.* at *8-9.

Fourth, the Final Rule's "attestation" requirement comprises yet another impermissible "limit." *Purl*, 2024 WL 5202497, at *9. Under it, "[a] covered entity ... may not use or disclose protected health information potentially related to reproductive health care for purposes specified in [the 2024 Rule] without obtaining an attestation[.]" 89 Fed. Reg. at 33,063. And the Final Rule imposes strict requirements for a valid "attestation." "The requesting agency must say the information will not be used for a prohibited purpose; must not contain any extra, nonrequired statements; must be believable to a reasonable covered entity; must contain a specific description of the sought information; must contain a statement that a covered entity could be subject to penalties for a HIPAA violation; must be in plain language; and must be signed." *Purl*, 2024 WL 5202497, at *9.

While even a proforma submission would amount to some "limit" on States' authority, *id.* at

*8-9, the attestation requirement is not the box-checking exercise HHS claims, *see* 89 Fed. Reg. at 33,030. The purpose of an investigation is to gather unknown information. *See* Kreutz Decl. ¶ 16. Yet the Final Rule requires investigators to complete attestations under threat of criminal liability with imperfect knowledge of the possible misconduct. That chills investigators' ability and willingness to comply with the attestation requirement, limiting their access to necessary information.

Nor is the Final Rule's attestation requirement a barrier just for the requesting party. *Purl*, 2024 WL 5202497, at *9. If any of the requirements for a valid attestation is not met, the covered entity "may not use or disclose" the requested information. 89 Fed. Reg. at 33,063. The "covered entity" is responsible for evaluating the "attestation" and if it is "defective" then they are "not in compliance" if they disclose the information. *Id.* Thus, even after an investigator provides an attestation, the covered entity (perhaps themselves subject to investigation) must scrutinize its contents and may withhold disclosure.

Fifth, on top of all that, the Final Rule directs covered entities to "*presume*" that the care provided by others was lawful "unless they know or are reasonably shown otherwise." *Purl*, 2024 WL 5202497, at *8 (emphasis in original). In this way, too, the Final Rule places a thumb on the scale for non-disclosure. The default becomes for covered entities to withhold information. And overcoming this presumption requires state investigators to proffer highly fact-specific showings about investigations they are seeking to initiate. Again, that puts the cart before the horse, since often the purpose of records requests is to gather further facts about suspected misconduct.

It may be that these "hurdles, at the end of an interpretive process," do not "outright *bar*" use or disclosure of requested information. *Id.* But the complex steps and analyses that the Final Rule requires of covered entities and requesting parties inhibits States' authority by "slow[ing] down," *id.*, "procedures … for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention," 42 U.S.C. § 1320d-7(b). These are exactly

the types of restraints and impediments that Congress expressly forbade. Thus, the Final Rule exceeds HHS's statutory authority and should be "set aside." 5 U.S.C. § 706(2)(C).

2. HHS cannot retreat to its general rulemaking authority as grounds for rewriting Congress's express prohibition against limiting States' authority. Section 1320d-7(b) nowhere "expressly delegate[s] to [HHS] the authority to give meaning to a particular statutory term," specifically "limit." *Loper Bright*, 603 U.S. at 394 (cleaned up). Indeed, that section contains no delegation of regulatory authority. Instead, HHS's authority to propose regulations governing "[t]he uses and disclosures of [health] information that should be authorized or required" is found elsewhere in HIPAA. Pub. L. No. 104-191 § 264(b)(3); *see also* 42 U.S.C. § 1320d-2. But the "statutes that *Loper Bright* cited as examples of delegations" warranting "deference don't only have broad language. They pair that language with words that expressly empower the agency to exercise judgment." *Moctezuma-Reyes v. Garland*, 124 F.4th 416, 420 (6th Cir. 2024). HIPAA's grants of rulemaking authority to HHS do not pair "broad language" with "words expressly empower[ing]" HHS to define "limit." Nor do they expressly sanction rules to restrict States' use or disclosure of health information for public health purposes. That lack of express authorization forecloses the Final Rule, since HHS "has no power to act … unless and until Congress confers power upon it." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

Worse still for HHS, Congress made clear that "*[n]othing*" in HIPAA shall impose limits on States' authority with respect to policing public health and welfare. 42 U.S.C. § 1320d-7(b) (emphasis added). "Nothing" means nothing, including HHS's general authority to issue regulations and HIPAA's general preemption provision in § 1320d-7(a). So notwithstanding HHS's authority to issue certain regulations governing "[t]he uses and disclosures of [health] information that should be authorized or required," Pub. L. No. 104-191 § 264(b)(3), Congress specifically mandated that HHS's authority could not be wielded to override States' authorities recognized in § 1320d-7(b).

The novelty of HHS's disclosure limits on "reproductive health care" information reinforces

HIPAA's proper scope. "[W]hen an Executive Branch interpretation was issued roughly contemporaneously with enactment of the statute and remained consistent over time" it might be entitled to respect in interpreting the law. *Loper Bright*, 603 U.S. at 370. But the Final Rule comes well after HIPAA's enactment, and HHS admits that the rule was a direct response to the Supreme Court's decision in *Dobbs*. 89 Fed. Reg. at 32,987-88. Thus, HHS's position that the Final Rule's new limits on the disclosure and use of "reproductive health care" information do not conflict with Congress's contrary directive in 42 U.S.C. § 1320d-7(b) is not entitled to deference.

In any event, HIPAA authorizes HHS to promulgate "standards with respect to the privacy of individually identifiable *health* information." Pub. L. No. 104-191 § 264(a) (emphasis added). Nowhere does HIPAA authorize HHS to shield from authorities information that is not "health information." And the statute does not shield information that is evidence of legal wrongdoing under state law. Yet the Final Rule rests on the proposition that health information protected from disclosure to state authorities includes information that a State believes is "evidence" of a violation of state law. *See* 88 Fed. Reg. at 23,516. No fair reading of health information permits that view. And if Congress had meant to permit such a shield, it knew how. *See* Dkt #1-2 at 8 (citing Pub. L. No. 104-191 § 248(a)). But HIPAA has no express limitation for disclosures with respect to state-law investigations.

3. Bedrock interpretative cannons confirm that HHS lacks authority to specially restrict "reproductive health care" information under HIPAA. Start with the major questions doctrine. Congress is expected to "speak clearly when authorizing an agency" like HHS "to exercise powers of vast economic and political significance." *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2021) (per curiam) (internal quotation marks omitted). HHS admits that the Final Rule was a direct response to the Supreme Court's decision to return abortion regulation to the States, 89 Fed. Reg. at 32,987-88, and few issues in our nation's history match the "political significance" of abortion regulation. *See Dobbs*, 597 U.S. at 229 ("[*Roe v. Wade*] sparked a national controversy that has embittered our political culture

for a half century."). Thus, had Congress intended to empower HHS to regulate "reproductive health care" information differently than all other forms of patient health information under HIPAA it needed do so "clearly," not in a "cryptic … fashion." *West Virginia v. EPA*, 597 U.S. 697, 716, 721 (2022) (citations omitted). But HHS cannot point to *any* language—let alone clear text—conferring it with power to create heightened disclosure regimes for "reproductive health care" information.

Next, consider the federalism cannon. *See* Dkt. #1-2 at 8-11. "Congress should make its intention clear and manifest if it intends to preempt the historic powers of the States." *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) (internal quotation marks and citation omitted). "This plain statement rule is nothing more than an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991). Public health, *Kentucky*, 23 F.4th at 599, and punishing "local criminal activity," *Bond*, 572 U.S. at 858, are core sovereign interests. And nothing in HIPAA provides clear notice that Congress intended to upend them. Rather, Congress expressly *preserved* States' power to obtain information from covered entities to promote these sovereign priorities. 42 U.S.C. § 1320d-7(b). Without "unmistakably clear language" in HIPAA countermanding Congress's otherwise expressed intent to preserve States' traditional authorities, HHS lacks statutory authority for the Final Rule. *See Gregory*, 501 U.S. at 460 (citation omitted).

Finally, constitutional-avoidance principles defeat any claim that the Final Rule's new disclosure limitations are lawful. "[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, [a court's] duty is to adopt the latter." *United States ex rel. Att'y Gen. v. Del. & Hudson Co.*, 213 U.S. 366, 408 (1909); *see also* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 247 (2012). And if Congress had intended to grant HHS the power it claims under the Final Rule, significant concerns boil to the surface under the non-delegation doctrine and Due Process Clause.

Congress delegated some legislative power to HHS by directing the agency to address patients' rights under HIPAA, the "procedures that should be established for the exercise of such rights," and the "uses and disclosures" of patients' "information that should be authorized or required," Pub. L. No. 104-191 § 264(b). *See INS v. Chadha*, 462 U.S. 919, 952 (1983) ("legislative" acts have "the purpose and effect of altering the legal rights, duties and relations of persons ... outside the legislative branch."). But while Congress may "obtain[] the assistance of its coordinate Branches" by delegating legislative power, it must "lay down … an intelligible principle" to guide the delegee. *Panama Refin. Co. v. Ryan*, 293 U.S. 388, 429-300 (1935) (citation omitted). And without the constraints that Congress put in place under § 1320d-7(b), HHS's authority to set rules on the "uses and disclosures of [private] information" is essentially boundless, raising serious non-delegation concerns. *See id.*

The Final Rule also raises serious due-process questions, particularly given HIPAA's stiff criminal penalties. Most problematic, the Final Rule's "lawful"-care provision requires covered entities and state agencies to render layers of *legal* judgments on questions that are unsettled and beyond their ken. *See infra* 21-22. Given HHS's flip-flopping positions on issues like abortion and transgender-related care,[6] there is serious risk of "arbitrary and discriminatory enforcement" contrary to due process. *See Meriwether v. Hartop*, 992 F.3d 492, 518 (6th Cir. 2021). Applying the clear language of 42 U.S.C. § 1320d-7(b) and rejecting HHS's improper claim of authority under HIPAA in the Final Rule avoids these thorny constitutional questions. *See Jennings v. Rodriguez*, 583 U.S. 281, 286 (2018).

C. The Final Rule is arbitrary and capricious.

An agency action must stem from "reasoned decisionmaking," or else it is "arbitrary and capricious" and should be set aside. *See Atrium Med. Ctr. v. HHS*, 766 F.3d 560, 567 (6th Cir. 2014) (citation omitted). In promulgating a rule, an agency may not rely "on factors which Congress has

[6] *Compare*, *e.g.*, HHS, *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522, 37,571-78 (May 6, 2024), *with* Executive Order 14,168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government* (Jan. 20, 2025), https://perma.cc/3XH2-YVYU.

not intended it to consider" or fail "to consider an important aspect of the problem." *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). But HHS did so here.

HHS allegedly sought to "strike an appropriate balance between ensuring health care privacy and conducting law enforcement activities." 89 Fed. Reg. at 32,993. To strike its asserted balance, HHS has imposed disclosure prohibitions related to "reproductive health care," a phrase HHS defined so as to sweep in nearly any form of health care. *See id.* at 33,063. After all, the human body's organ systems are interrelated, so nearly any healthcare "affects the health of an individual in [*some*] matters *relating to* the reproductive system and to its *functions* and *processes*." *Id.* (emphases added). That concern is not hypothetical: Health Facilities investigators, for example, have had requests for PHI related to a psychiatric facility denied. Zeigler Decl. ¶ 8-10. When commenters made HHS aware of that possibility, 89 Fed. Reg. at 33,006, HHS shrugged, *id.* at 33,007. So investigators and covered entities must sort things out among themselves without the guidance the APA requires from the agency. *See id.* at 33,063.

HHS's explanatory failures do not end there. The Final Rule requires PHI-request recipients to assess the legality of the "reproductive health care" involved in the request. *Id.* at 33,063. But, in general, request recipients will be medical, not legal, professionals, ill-suited to assessing law. *Purl*, 2024 WL 5202497, at *8. Making matters worse, the Final Rule forces request recipients to presume "reproductive health care" provided by others is lawful, unless the request recipient has "[a]ctual knowledge that the reproductive health care was not lawful" or the investigator "supplie[s]" sufficient "[f]actual information" to "demonstrate[] a substantial factual basis that the reproductive health care was not lawful." 89 Fed. Reg. at 33,063. That presumption applies even though instances of the Final Rule's "reproductive health care" are illegal in many jurisdictions, meaning health professionals making the assessment required by the Final Rule must *ignore* what they may know about the law. *See, e.g.*, Tenn. Code Ann. § 39-15-213(b). HHS officials have argued that some federal statutes preempt state

medical regulations in areas the Final Rule implicates. *E.g.*, Br. of U.S. at 20-27, *Moyle v. United States*, Nos. 23-726 & 23-727 (U.S. Mar. 21, 2024).

The upshot: Under the Final Rule, PHI-request recipients must presume some broadly defined category of "reproductive health care" is legal, even when it is not, and then do legal analysis, even though they are not lawyers, to fulfill a request. The Final Rule flunks rationality on those fronts.

Independently, the Final Rule's vesting of assessment power in PHI-request recipients has consequences HHS never considered, let alone adequately justified. The criminal liability attached to improper disclosure creates an incentive for PHI-request recipients to deny requests. *See* 42 U.S.C. § 1320d-6. Yet the Final Rule provides no recourse for a denied requestor to challenge the denial. *See* 89 Fed. Reg. at 33,063-66. HHS's choose-your-own-adventure approach perversely empowers suspected lawbreakers to hinder an investigation into themselves. Again, the Final Rule provides no justification for such a scheme, *see* 89 Fed. Reg. at 33,063-66, which thwarts the ancient maxim that "[n]o man is allowed to be a judge in his own cause." *The Federalist* No. 10, at 79 (James Madison) (Clinton Rossiter ed., 1961).

The Final Rule's paperwork gums up vital investigations without good reason. Investigators must attest that the Final Rule permits disclosure when there is a potential connection to "reproductive health care," which can encompass almost any request. *See* Zeigler Decl. ¶¶ 8-11. HHS has not explained how that scheme abides HIPAA's statutory prohibition on rules that "invalidate or limit" States' ability to regulate public health. 42 U.S.C. § 1320d-7(b). More mundane but more frequent is the Final Rule's requiring investigators to engage in difficult legal work just to get a request out the door. Spahr Decl. ¶¶ 15-20; Kreutz Decl. ¶¶ 10-14, 16-18. HHS did not adequately explain why those burdens on States' investigative authority are reasonable. And with all those burdens come costs, which HHS did not adequately account for.

II. The Entire Rule Should Be Vacated.

Section 706 of the APA instructs that reviewing courts "shall … hold unlawful and set aside agency action" that violates an agency's organic statute, the U.S. Constitution, or the APA's bar on arbitrary-and-capricious and procedurally invalid decision-making. 5 U.S.C. § 706(2). A vacatur order—unlike an injunction and other in personam relief—would act on the Final Rule itself by denying it legally operative effect and treating it as void as to all regulated parties. Vacatur is the "ordinary result" in APA cases challenging a Final Rule's statutory or constitutional authority and aligns with the APA's history and "countless decisions" from the Supreme Court that have "vacated agency actions, including agency rules." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 829-33 (2024) (Kavanaugh, J., concurring) (collecting authorities); *see also Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 52 (D.D.C. 2020) (Jackson, J.) (vacatur of a rule "for everyone" is normal APA remedy).

The Final Rule's legal flaws warrant vacatur across the board. *Cf. Ohio v. EPA*, 603 U.S. 279, 293-96 (2024); *Tennessee v. Cardona*, No. 24-5588, 2024 WL 3453880, at *4 (6th Cir. July 17, 2024). HHS's lack of statutory authority to adopt the Final Rule renders the Rule invalid and requires vacatur since an "illegitimate agency action is void *ab initio*" regardless of further agency justification. *Texas v. Cardona*, No. 4:23-cv-604-O, 2024 WL 2947022, *46 (N.D. Tex. June 11, 2024). Indeed, the core premise of HHS's Final Rule is an unlawful one: That HIPAA empowers HHS to create new categories of disclosure based upon substantive judgments about the value of particular medical procedures. So too, HHS's pervasive arbitrariness renders the Final Rule "invalid in its entirety." *Tennessee v. Cardona*, 737 F. Supp. 3d 510, 570 (E.D. Ky. 2024).

III. At a Minimum, Plaintiffs Are Entitled to Preliminary Relief.

Though this case is ripe for final judgment, this Court should at least enjoin the Final Rule's application to the Plaintiff States, their HIPAA-covered entities, and their investigative agencies. Or the Court should stay the Final Rule under 5 U.S.C. § 705. In addition to having likely merits success,

Plaintiffs satisfy the remaining preliminary-relief factors.

Irreparable Harm: The Final Rule has and will continue to inflict irreparable harms on the Plaintiff States. *First*, the Final Rule injures the Plaintiff States' sovereignty. States' sovereign police powers include powers to regulate "to promote the public health, the public morals, or the public safety," *Chicago, Burlington & Quincy Ry. Co. v. Illinois*, 200 U.S. 561, 592 (1906), and to punish "local criminal activity," *Bond*, 572 U.S. at 858. "[C]ontrol over the public fisc" is also "central to a state's sovereignty." *T.M. ex rel. H.C. v. DeWine*, 49 F.4th 1082, 1095 (6th Cir. 2022) (Readler, J., concurring). Yet the Final Rule infringes these interests. It hampers the Plaintiff States' ability to regulate to those ends by slowing or preventing state investigations, leaving patients and the public vulnerable. *See, e.g.*, Zeigler Decl. ¶¶ 8-11; Dietz Decl. ¶¶ 20-21; Joiner Decl. ¶¶ 8-9. And delays to billing-fraud investigations may impact the amount the States are ultimately able to recover. *See* Kreutz Decl. ¶ 20 (delay may push some misconduct outside the statute of limitations for recovery). Such "invasions of state sovereignty" are irreparable. *Kentucky*, 23 F.4th at 611 n.19.

Second, the Plaintiff States must expend resources to comply with the Final Rule's byzantine procedural burdens. *See, e.g.*, Kreutz Decl. ¶¶ 16-18; Spahr Decl. ¶ 15; Traxler Decl. ¶¶ 17-18; Targia Decl. ¶¶ 16-18. As HHS acknowledged, the Final Rule necessitates "new or modified policies and procedures" was well as "trainings." 89 Fed. Reg. at 33,056. And both covered entities and investigators have ongoing obligations to evaluate requests for information and attestations. Even if Plaintiff States later prevail against the Final Rule, they cannot recover money damages from the federal government. *Kentucky*, 23 F.4th at 611 n.19. Such "unrecoverable compliance costs" are irreparable harm too. *Kentucky v. Biden*, 57 F.4th 545, 555-56 (6th Cir. 2023).

Equities and Public Interest: Courts weighing the equities must consider "the competing claims of injury and ... the effect on each party of the granting or withholding of [that] requested relief." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008) (citation omitted). Here, HHS would

suffer no harm from sticking to the scheme they themselves "designed" specifically to balance patients' privacy interests against State's investigatory authority. 65 Fed. Reg. at 82,683. Indeed, covered entities and State investigators have successfully operated under the Privacy Rule for a quarter century. By contrast, HHS previously warned that imposing disclosure requirements "significantly more" stringent than the Privacy Rule could "unduly compromise[]" States' "ability to protect the public interest." *Id.* That warning has proven prescient, *supra* 9-10 (collecting cites), as the Final Rule has significantly stymied the States' investigations into fraud, abuse, and other matters of public interest.

Preliminary relief also serves the public interest. The public has an interest in safe, professional medical care. Yet the Final Rule is halting investigations into fraud, abuse, and potential substandard care, preventing investigators from protecting the public fisc and ensuring the well-being of patients within their borders. HHS cannot credibly claim a countervailing public interest in promoting broader abortion access, since the Constitution leaves that choice to States. Regardless, Congress has not conferred HHS with "the power to regulate" in the challenged manner, so it is not courts' role to "weigh [the] tradeoffs" of HHS's pursuit of self-proclaimed "desirable ends." *Nat'l Fed'n of Indep. Bus. v. OSHA*, 595 U.S. 109, 120 (2022) (per curiam); *Ala. Ass'n of Realtors*, 594 U.S. at 766. By contrast, "'the public interest lies in a correct application' of the law." *Kentucky*, 57 F.4th at 556 (citation omitted). That is truer still when an agency's unlawful action "threatens state sovereign interests," *Kentucky v. Yellen*, 67 F.4th 322, 327 (6th Cir. 2023) (Bush, J., statement regarding denial of reh'g en banc)—as HHS's Final Rule does here, *supra* 11-12, 24.

CONCLUSION

For all these reasons, this Court should enter summary judgment for the Plaintiff States and set aside the Final Rule as unlawful. At a minimum, this Court should enter preliminary relief against the Final Rule pending the case's resolution.

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Respectfully submitted,

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** Application for Pro Have Vice pending
*** Application for Pro Hac Vice forthcoming
**** Application for full admission pending

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served via the Court's electronic filing system on this 7th day of February, 2025 to all counsel of record. The document was further served via email on the following, who is representing the Defendants in two parallel challenges to the Final Rule in the United States District Court for the Northern District of Texas:

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